Remarks

Applicants herein traverse and respectfully request reconsideration of the rejections of the claims in view of the following remarks.

Claims 21-23, 25-27 and 29 are pending in the application. Claims 21-23, 25-27 and 29 have been rejected.

Claims 21-22, 25-26 and 29 have been rejected under 35 U.S.C. §103(a) as being unpatentable over EP 0322134 (EP'134) in view of U.S. Patent 5,996,424 (Tan et al.).

In particular, the Examiner states:

> EP 0322134 discloses a method of packaging and steam sterilizing a pharmaceutical product such as saline solution. A semi-rigid squeezable polypropylene bottle is filled with a pharmaceutical product and once the bottles are sealed and prepared for sterilization they are inserted into an autoclave. The individual bottles are filled to the maximum internal volume with the pharmaceutical product thus eliminating any air present. The elimination of the air inside the bottle prevents the formation of dimples in the polypropylene during the sterilization. The autoclave serves the purpose of sterilizing the bottles using an application of steam at temperatures of 121°C (see Column 3, line 29 – column 6, line 12 and figures 1 and 2). EP 0322134 further teaches that the lids and caps of the bottles can be formed of other polymeric materials other than polypropylene (see column 3, lines 29-49). However, EP 0322134 does not disclose a cap that consists of a material with a modulus of elasticity different from polypropylene.
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> Tan et al. disclose a polymeric bottle for obtaining, storing, and transporting chemical samples. The polymeric bottle comprises a bottle portion (38) and a cap portion (22). Preferably the bottle portion and the cap portion are made from a material selected from the group consisting essentially of chemical resistant polymers.
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> Furthermore, it is disclosed that the bottle portion (38) and the cap (22) do not have to be made out of the same material. For example, body (38) can be made from high-density polyethylene, while the cap (22) can be made from a low density polyethylene (see column 11, lines 1-40). This reference has been relied upon to teach that it is well known to utilize a material for the cap having a different modulus of elasticity that the material used for the body portion.
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> Therefore, it would have been obvious to one of ordinary level of skill in the art at the time the invention was made to modify the invention of EP 0322134 and construct the cap from a material having a different modulus of elasticity than the bottle body, since Tan et al. teaches that it is well known to utilize a material for the cap different than the material used for the bottle body. Furthermore, it would have been obvious to use a polyethylene

such as high-density polyethylene for the cap because Tan et al. teaches that polyethylene is a known material used for constructing polymeric articles such as bottles and caps.

Additionally, it would have been obvious to one having ordinary level of skill in the art at the time the invention was made to use a high density polyethylene as the cap material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416."

Applicants disagree with the Examiner's conclusion and respectfully submit that the combined cited references do not make obvious the claimed subject matter as defined in independent Claims 21 and 26 for the reasons stated below.

EP'134 describes a method of preparing and sterilizing a pharmaceutical package containing a saline solution. In this method, a polypropylene bottle is filled with a saline solution, capped and then autoclaved. EP'134 further indicates that while the caps are preferably formed of a polypropylene, other polymeric materials might also be suitable for the bottles and caps (see column 3, lines 29-49). As acknowledged by the Examiner, there is no teaching or specific suggestion in EP'134 that the material utilized for the cap consist of a material having a modulus of elasticity different from the material of the polypropylene bottle as set forth in independent Claims 21 and 26. Further, there is no teaching or specific suggestion in EP'134 that a polypropylene bottle/cap consisting of a material having a modulus of elasticity different from the material of the polypropylene bottle can be sterilized as set forth in independent Claims 21 and 26.

With respect to the Examiner's statement pertaining to Tan et al. that this reference has been relied upon to teach that it is known to utilize a material for the cap having a different modulus of elasticity than the material used for the body portion, it is respectfully submitted that the Examiner's statement indicates that he has not considered the Tan et al. disclosure as a whole, but instead has chosen certain features described in Tan et al. to combine with the EP'134 disclosure to allegedly arrive at the presently claimed invention.

In this regard, the Examiner's attention is directed to MPEP §2141.02 which clearly states that when ascertaining the differences between the prior art and the claims at issue, not only must the claimed invention be considered as a whole, but also the prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.

Tan et al. describe a method for manufacturing a low contamination sampling bottle for the sampling, storage and transport of liquid chemical samples, particularly liquid chemicals used in processing semiconductors (see column 1, lines 32-67 and column 2, lines 1-10). Tan et al. indicate in the Background Art section prior to describing their method of manufacturing a low contamination sampling bottle that the liquid chemicals used in processing semiconductors must be kept very pure and that the contaminants of most concern are typically metal particles, and anionic or organic contaminants (see column 2, lines 5-29). The liquid chemical samples must also be pure at the point of use, e.g., at a semiconductor manufacturing tool, at the wet station, etc. (see Tan et al., column 2, lines 29-32). Accordingly, this requires that the liquid chemicals are not only pure at the bulk storage container but they also must not acquire undesirable impurities as they are being distributed by the Bulk Chemical Distribution System (see Tan et al., column 2, lines 32-35). Tan et al. make clear that finding a sampling bottle that is clean enough for the application and also compatible with corrosive and concentrated chemicals is a problem in the prior art (see column 2, lines 61-64).

Tan et al. indicate that with their method clean chemical samples can be obtained without introducing trace contaminants such as metals, anions, and organics at the parts per billion levels (see column 5, lines 25-28). The method involves blow molding a bottle within the blow molding machine using a low contamination ("clean") resin and a low contamination ("clean") gas (see Tan et al., column 5, lines 30-50). The term "clean resin" means that the resin should contain less than 1 part per billion of leachable metal contaminants and 1 part per billion of leachable anionic and organic contaminants after being molded into a product (see Tan et al., column 8, lines 46-50). The low contamination resin is specifically selected from the group consisting essentially of chemically resistant hydrocarbon polymers, e.g., polyethylene and fluorocarbon polymers (see Tan et al., column 5, lines 35-40). A cap made of chemically resistant hydrocarbon polymers as described for the bottle is immediately affixed to a threaded neck of the bottle as it comes off the mold to produce a fluid-tight seal between the cap and the bottle (see Tan et al., column 5, lines 50-59). Tan et al. also indicate that by producing the low contamination sampling bottle by this method, it is not generally necessary to pre-clean or pre-condition the bottle prior to obtaining a chemical sample (see column 5, lines 60-63). Tan et al. further indicate that by capping the bottle immediately after production few contaminants are able to come into contact with the internal surfaces of the bottle. Tan et al. further make clear that the bottle can be used in three different ways: 1) to obtain a sample of a liquid from a drum, bath or open body of liquid; 2) to store the chemical sample; and 3) to transport the chemical sample (see column 12, lines 40-50).

Accordingly, Tan et al. is concerned with manufacturing a sampling bottle for liquid chemical samples used in processing semiconductors, wherein the sampling bottle has few contaminants, particularly metal contaminants leaching from the material constituting the bottle.

In Tan et al., the bottle coming off the mold is immediately capped and subsequently the cap is removed to fill the bottle with the liquid chemical sample. Importantly, Tan is not concerned about solving the problem of sterilizing a closed, squeezable bottle containing an ophthalmic liquid, gel or ointment.

As acknowledged by the Examiner at Page 4, the sampling bottle described by Tan et al. can comprise a bottle portion made of high density polyethylene and a cap made of low density ethylene. Tan et al., however, fail to teach or specifically suggest: 1) the combination of a polypropylene bottle with a cap consisting of a material with a modulus of elasticity different from polypropylene; or 2) that such a combination of polypropylene bottle/cap containing an ophthalmic liquid, ointment or gel can be autoclaved utilizing conditions as set forth in independent Claims 21 and 26.

Indeed, Tan et al. discourage use of sampling bottles made of polypropylene. In particular, Tan et al. state at column 3, lines 26-31, that:

> "Other types of samples devices include rigid spouts with pumping mechanisms, pressure differential systems, bailer systems, etc. However, all of these sampling apparatus suffer from one or more of the following drawbacks:
>
> 1) they are made from chemically incompatible material such as **polypropylene**;..."

Tan et al., with respect to the use of polypropylene as the material for sampling bottles further state at column 4, lines 44 to column 5, line 10 that:

> "Some sampling bottle are made by a process known as "blow molding." One type of such prior art sampling bottles is a sampling bottle made of **polypropylene** resin that is provided with a snap-on cap. Such a prior art bottle is suitable for certain non-hazardous liquids such as water, but is not useful or safe for storing or transporting hazardous samples of most chemicals used in semiconductor manufacturing processes.....It should also be noted that **polypropylene** bottles are not appropriate for the collection or transport of hazardous liquids in that they are incompatible with many corrosive liquids, and often do not have a leak-proof threaded cap as required under the U.S. Department of Transportation regulations. Therefore, there is no interest in the semiconductor manufacturing industry in using inexpensive **polypropylene** bottles, even if they are pre-cleansed, for holding and shipping chemical samples. Further, there is no interest in using **polypropylene** samplers, such as **polypropylene** bellows pump available at Acron Industries (Livonia, Mich) for the obtainment of liquid samples in the semi-conductor industry for similar reasons."

With regard to the Tan et al. disclosure pertaining to the use of polypropylene bottles, Applicants respectfully direct the Examiner's attention to the Federal Court's instruction in *In re*

Gurley, 31 USPQ2d 1131 (Fed. Cir. 1994), wherein the Court instructed that a prior art reference "teaches away" when one of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the prior art reference, or alternatively, would be led in a direction divergent from the path that was taken by the applicant.

In view of the above instruction, it can fairly be said that Tan et al., in describing the disadvantages associated with utilizing polypropylene sampling bottles to sample, store or transport chemicals, specifically teach away from utilizing polypropylene for the bottle portion of the Tan et al. sample bottle. Accordingly, one skilled in the art armed with the teaching of Tan et al. as a whole would be led in a direction divergent from the path that was taken by the Applicants and the EP'134 reference, that is, one skilled in the art would not have been motivated to choose polypropylene resin as the material for the bottle portion of a bottle.

Further, in view of the teaching in Tan et al. of utilizing the chemically resistant polymers, polyethylene or fluorocarbon polymers, as the material for the bottle portion of the sampling bottle, and the teaching away from utilizing polypropylene as the material for the bottle portion of the sampling bottle, one skilled in the art reading the disclosure of Tan et al. would not have been motivated to substitute the polyethylene or fluorocarbon polymer with polypropylene to make the bottle portion of the sampling bottle.

In summary, Tan et al. as a whole: 1) teach the use of the chemically resistant polymers, polyethylene or fluorocarbon polymers, as the material for the bottle portion of the sampling bottle; 2) fail to teach or specifically suggest the use of polypropylene as the material for the bottle portion of the sampling bottle; 3) teach away from using polypropylene as the material for the bottle portion of a bottle; 4) teach that the sampling bottle is filled with the liquid chemical sample at a time subsequent to capping the bottle; and 6) fail to be concerned with the problem of completely sterilizing a polypropylene bottle/cap containing an ophthalmic liquid, ointment or gel.

In contrast to the teachings of Tan et al., EP'134: 1) teaches a closed pharmaceutical package comprised of a polypropylene bottle/cap containing a pharmaceutical liquid, wherein the bottle is filled with the pharmaceutical liquid prior to capping the bottle; 2) teaches a method of sterilizing the pharmaceutical package containing the pharmaceutical liquid; and 3) fails to be concerned with the problem of minimizing the level of metal contaminants that can leach from the sampling bottle into the liquid sample. From the discussion above, it is apparent that the pharmaceutical package composed of a polypropylene material and the method of preparing the package described in EP'134 are completely different from the sampling bottle made of polyethylene or fluorocarbon and method of preparing the bottle described in Tan et al. Accordingly, it is difficult to see how one skilled in the art when viewing the Tan et al. disclosure

and EP'134 as a whole, especially in view that EP'134 teaches use of a polypropylene bottle portion whereas Tan et al. teach away from use of a polypropylene bottle portion, would have been motivated to combine EP'134 with Tan et al.

Accordingly, since EP'134 and Tan et al. each viewed as a whole, are not combinable, it would not have been obvious to one or ordinary skill in the art at the time the invention was made to modify the invention of EP'134 and construct the cap from a material having a different modulus of elasticity than the polypropylene bottle portion to arrive at the presently claimed invention.

In view of the above, withdrawal of the rejection of Claims 21-23, 25-27 and 29 under 35 U.S.C. §103 is respectfully requested.

Claims 23 and 27 have been rejected under 35 U.S.C. §103(a) as being unpatentable over EP'134 and Tan et al. and further in view of U.S. Patent 4,357,288 (Oas et al.). In particular, the Examiner states:

> "EP 0322134 and Tan et al. do not teach the specific thickness of the polymeric bottles.
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> Oas et al. teaches a method of making a clear transparent polypropylene bottle.
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> More specifically, Oas et al. disclose that the polypropylene bottles are constructed so that they have a wall thickness on the order 15 mils to 30 mils (0.38 mm to 0.76 mm) (see column 3, line 65 to column 4, line 8).
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> Therefore, since Oas et al. teaches a polypropylene bottle having a wall thickness that falls within the applicant's claimed range, it would have been obvious to one of ordinary level of skill in the art at the time the invention was made to make the polypropylene bottles disclosed by EP 0322134 so that they have a wall thickness of 0.38 mm to 0.76 mm as taught by the polypropylene bottles manufactured by Oas et al."

Applicants disagree with the Examiner's conclusion and respectfully submit that the combination of EP'134, Tan et al. and Oas et al. does not make obvious Claims 23 and 27 for the reasons stated below.

Claims 23 and 27 depend from Claims 21 and 26, respectively. Accordingly, the arguments proffered above to address the rejection of Claims 21-22, 25-26 and 29 under 35 U.S.C. §103 as being unpatentable over the combination of EP'261 and Tan et al. apply equally well to this rejection, namely one skilled in the art reading EP'261 and Tan et al. as a whole would not be inclined to combine EP'261 with Tan et al. to arrive at the present invention.

Oas et al. describe a method of stretch blow molding crystalline polypropylene to produce bottles having a clear, gloss finish. While Oas et al. indicate the finished bottle can have a wall thickness of 15-30 mils, Oas et al. fail to teach or specifically suggest a closed, polypropylene bottle combined with a cap consisting of a material having a modulus of elasticity different from polypropylene or that such a combination of bottle/cap containing an ophthalmic liquid, ointment or gel can be autoclaved and avoid deformation. Accordingly, the combination of EP'261, Tan et al. and Oas et al. does not make obvious dependent Claims 23 and 27.

In view of the above, withdrawal of the rejection of Claims 23 and 27 under 35 U.S.C. §103(a) is respectfully requested.

The Examiner has also cited U.S. Patents 4,971,213 (Ishinabe et al.) and 4,754,892 (Retief) as allegedly being pertinent to Applicants' disclosure in that both patents teach a cap or lid manufactured from a high-density polyethylene.

Ishinabe et al. describe a plastic cap comprising *inter alia*, a top plate and a skirt hanging down from the peripheral edge of the top plate. The plastic cap is described as possessing an excellent pressure-resistant sealing property and excellent venting property (gas vent property) and is utilized to close carbonated drink-filled vessels. While Ishinabe et al. indicate that the plastic cap can be made of different resins such as polyethylene, polypropylene, and the like, Ishinabe et al. is merely concerned with solving the problem of venting gas that occurs in carbonated drink-filled vessels. Ishinabe et al. is completely silent on autoclaving a closed, squeezable polypropylene bottle containing an ophthalmic liquid, ointment or gel or that such a bottle should be made of polypropylene combined with a cap consisting of a material having a modulus of elasticity different from the bottle.

Retief describes a closure for a container comprising *inter alia*, a cap comprising a disc-shaped end panel wall, a cylindrical skirt wall extending from the peripheral edge of the end panel wall and an injection molded sealing member for sealing a container opening, the sealing member being located inside the cap on the inside of the cylindrical skirt wall and adjacent the end panel wall. While Retief describes that the cap can be made of polypropylene or high density polyethylene, this reference is completely silent on autoclaving closed, squeezable bottles containing an ophthalmic liquid, ointment or gel, or that such bottles to be autoclaved should be made of polypropylene combined with a plastic cap consisting of a material having a modulus of elasticity different from polypropylene.

Accordingly, Applicants do not consider Ishinabe et al. and Retief as being relevant to the presently claimed subject matter.

A good faith effort has been made to place the present application in condition for allowance. If the Examiner believes a telephone conference would be of value, he is requested to call the undersigned at the number listed below.

Respectfully submitted,

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